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PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Ethylene bisdithiocarbamates [Mancozeb, Maneb, and Metiram]. Summary of Percent Crop Treated (%CT), and Justification for Use of the 1990 EBDC Market Basket Survey in Dietary Exposure Assessments for Reregistration. Mancozeb DB Barcode No. D290139; Maneb DP Barcode No. D290140; Metiram DB Barcode No. D290137.

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The Agency is currently preparing human health risk assessments to support reregistration of products containing the active ingredients mancozeb, maneb and metiram. These three active ingredients are ethylenebisdithiocarbamate (EBDC) fungicides, and have similar use patterns for some crops. This memorandum has two purposes: (1) to summarize the percent crop treated information for each of the three EBDC active ingredients, provided by OPP's Biological and Economic Analysis Division (BEAD); and (2) to justify use of EBDC residue monitoring data in the current risk assessments.

From 1989 - 1992, the EBDCs were under Special Review for concerns about cancer risks from exposure to the common EBDC metabolite, ethylenethiourea (ETU), which is considered to be a likely human carcinogen. As part of the Special Review, and in order to conduct a highly refined

dietary exposure assessment, the EBDC registrants conducted a large-scale market basket survey (MBS) to determine EBDC and ETU residues in a variety of foods as close to the point of consumption as possible (i.e., grocery stores and small markets). The survey was completed in 1990, and the Special Review was concluded with the Final Determination (PD 4) on 3/2/92.

In the current assessments, HED intends to use the 1990 EBDC MBS results in highly refined acute, chronic and cancer dietary risk assessments for each of the EBDCs, as well as for ETU. Commodities for which market basket survey data are available include: dry beans ("fresh" and canned); broccoli (fresh and frozen), sweet corn (fresh, frozen and canned); celery; cucumber; head lettuce; meat; milk; onion; potato (fresh and frozen); and tomato (fresh, juice, ketchup, paste and puree). To the extent possible, these data may be translated to other commodities based on similarities in the crop type (e.g., fresh tomato residues could be translated to pepper and eggplant), assuming the use pattern is similar, and assuming that field trial data support such translations. For commodities that don't have MBS data, and/or for which no reasonable translations from monitored commodities are possible, field trial data reflecting label use patterns will be used in the dietary exposure assessments.

Factors affecting the magnitude and frequency of residues in monitoring samples, including the MBS data, are the use pattern - application rate and percent of crop treated - and the capability of analytical methods used to detect residues. The EBDC market basket survey data were generated over 10 years ago, but HED proposes using the data to the fullest extent possible in the current dietary exposure assessments. The expected magnitude and frequency of detected residues in the survey data are still considered, in general, relevant for the current use pattern in terms of the percent crop treated (%CT) and the amount applied per acre.

This conclusion is based on (1) BEAD's assessment of trends in EBDC usage for a wide variety of crops, and on the monitored crops; (2) the assessment of %CT for individual EBDCs, both current estimates and those used in the dietary exposure assessment completed in 1991; and (3) the registrants' updated market share, usage rate and %CT information presented to the Agency in SMART meetings conducted 10/98. The lack of significant changes in the overall EBDC use pattern during the last decade is largely due to the restrictions placed on total EBDC usage and application rates at the conclusion of the Special Review in 1992. The rate restrictions included rate reductions for some crops, so the residue levels detected in the MBS are considered, in general, to be the same as or higher than those expected in the same foods under current usage. HED notes that the 1990 MBS samples were analyzed using analytical methods still in use today for both enforcement and data collection purposes, with concomitant limits of detection and quantitation. Therefore, assumptions about nondetectable residues in the MBS survey data are acceptable for use in the current risk assessment.

All three EBDCs are broad spectrum contact fungicides, used on a variety of agricultural crops, turf and ornamentals. Mancozeb and maneb have the most food uses, while metiram food uses are limited to apples and potatoes. In terms of annual production and uses, mancozeb is the most significant, with over 6 million pounds of total domestic usage; crops with the largest market in

terms of pounds active ingredient (ai) are potatoes, fresh tomatoes and apples. Maneb domestic usage is estimated to be over 2 million pounds ai annually; crops with the largest markets in pounds ai are potatoes, peppers (bell and nonbell), and lettuce. Metiram domestic usage is estimated at over 600,000 pounds annually, with two-thirds of the pounds ai applied to apples, and one-third of the pounds ai applied to potatoes.

A table summarizing the BEAD %CT estimates for each EBDC on the relevant supported crops is attached (see Table 1) [based on BEAD Quantitative Usage Estimates dated 12/2/02, F. Hernandez]. These estimates were provided based on information generated by the US. Dept. of Agriculture (USDA) National Agricultural Statistics Service (NASS). The table also includes the %CT estimates (for most crops) that were used in the 1991 dietary exposure assessment; these estimates were used for the 1991 (dietary) cancer risk assessment for ETU, and should be considered similar to the current average %CT numbers, rather than the likely maximum. In addition to the information provided for each individual active, BEAD examined trends in EBDC usage during the 1990's, and concluded that there was no evidence of major changes in overall EBDC usage from the early to late 1990's, given the usual range of variability in usage estimates and normal fluctuations in usage from year to year [based on NASS and Doane's (proprietary) survey data].

The 1991 %CT estimates for almond, head lettuce, pears, pumpkins and bananas were less than those to be used in the ongoing dietary exposure assessments, indicating that the treated acreage these crops has increased since 1991. None of these commodities were monitored in the market basket survey, so crop field trial data will be used to assess dietary exposure to residues from these commodities; therefore, use of the MBS data will not underestimate exposure to residues in these crops and the associated commodities.

Additional information on %CT for individual crops/active ingredients was provided in a personal communication from Steve Nako, 7/21/03: potatoes, tomatoes (fresh and processed), sweet corn (fresh and processed) and head lettuce. The information is summarized in Tables 2 through 5. For both potatoes and tomatoes, the %CT has increased somewhat over time, indicating that the frequency of residue detections seen in the MBS data may be lower than currently reflected under the current use pattern; however, the magnitude of residues is not likely to have increased, based on seasonal application rates. For these commodities, a more refined assessment of dietary exposure and risk may be undertaken, with potential adjustments for the increased frequency of detections, in the event that potatoes and/or tomatoes are considered to be significant risk contributors. For both sweet corn and head lettuce, the MBS data are considered to be representative of the current use pattern.

Table 1. BEAD Percent Crop Treated Estimates for Mancozeb, Maneb and Metiram.

Crop	Mancozeb %CT		Maneb %CT		Metiram %CT		Used in PD4
	Avg.	Max.	Avg.	Max.	Avg.	Max.	Average EBDC
Commodities Monitored in the EBDC/ETU Market Basket Survey (MBS)							
Beans, Dry			1.2	4.3			24
Broccoli			8.4	15			10
Cucumber	18	32	9.6	21			60
Lettuce, head			57	68			40
Onions (dry/green)	38	77	10	19			65 (dry) 15 (green)
Potatoes	36	50	8.2	16	3.5	11	60
Sweet corn, fresh	18	27	4.2	13			30
Sweet corn, proc.	12	22	1.3	5			30
Tomatoes, fresh	49	80	5.8	11			40
Tomatoes, proc.	12	22	3.4	11			40
Meat	NA						NA
Milk	NA						NA
Grape Wine and Juice Monitoring (mancozeb, targeted to treated grapes in NY)							
Grape	9	14	1.3	5.1			21
Commodities Not Monitored in the EBDC/ETU Market Basket Survey (MBS)							
Almond			12	18			3
Apple	26	41	0.2 (<1)	0.3 (<1)	11	18	55 (fresh) 10 (proc.)
Asparagus	16	34					
Barley*	0.2 (<1)	0.9 (<1)	0.06 (<1)	0.1 (<1)			<1
Brussels sprouts			No	Data			10
Cabbage-tight			17	28			16
Cabbage-loose			10	19			
Cantaloupe	8	10	1.3	3.1			35
Carrots	8	13					50
Cauliflower			0.4	2.3			20
Collards			9	17			90
Corn, field*	0.00 (<1)	0.00 (<1)	0.00 (<1)	0.01 (<1)			<1
Corn, pop.			No	data			
Cotton*	0.2 (<1)	0.8 (<1)	0.04 (<1)	0.07 (<1)			2
Cranberry	No	data	<1	<5			10
Eggplant			50	69			60
Endive			No	data			50
Flax*			No	data			
Garlic			10	19			15
Kadota figs			No	Data			

Table 1. BEAD Percent Crop Treated Estimates for Mancozeb, Maneb and Metiram.

Crop	Mancozeb %CT		Maneb %CT		Metiram %CT		Used in PD4
	Avg.	Max.	Avg.	Max.	Avg.	Max.	Average EBDC
Kale			5	8			90
Kohlrabi			No	Data			
Lettuce, leaf			49	75			60
Melons, honeydew	8.2	13	4.1	11			35
Mustard greens			6	15			90
Oats/Rye*			0.02 (<1)	0.03 (<1)			<1
Papaya, dom/import	No	Data	No	Data			
Peanuts*	0.9 (<1)	2.3	0.4 (<1)	0.6 (<1)			6
Pears	32	51			0.7 (<1)	1.5	15
Peppers, bell			34	51			55
Peppers, nonbell			29	45			55
Pumpkins			39	55			30
Rice*	0.00	0.00	No	data			
Safflower*			No	data			
Sorghum*			No	data			
Squash, (sum/win)	41	86	15	28			45
Sugar beets	1.3	2.9	1.3	3.3			5
Tobacco	1.3	2.7					
Turnip tops			No	data			90
Walnuts (S18)			4.3	8.5			
Watermelon			8.3	10			35
Wheat, spring*	0.9 (<1)	2.3	0.07 (<1)	0.12 (<1)			0.3
Wheat, winter*	0.2 (<1)	0.4 (<1)	0.02 (<1)	0.04 (<1)			0.3
Banana (Import)	100	100	<5	<5			80

* Designates a seed treatment use.

Table 2. Yearly Estimates of EBDCs Usage on Fall Potatoes.*

Year	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2001
Mancozeb											
Total Amount (Lbs AI) Applied	1,063	1,415	1,590	1,796	2,197	2,066	814	2,305	554	2,775	1,877
Avg Number of Apps/Season	3.3	3.5	3.4	3.5	3.9	3.4	2.5	2.9	6.2	3.1	3.7
Percent of Crop Treated	26	32	41	42	43	45	36	64	82	65	51
Avg App Rate (Lbs AI/Ac/Trt)	1.11	1.14	1.08	1.09	1.15	1.17	1.16	1.31	1.10	1.21	1.10
Seasonal App Rate (Lbs AI/Ac/Yr)	3.70	3.95	3.65	3.85	4.52	4.04	2.87	3.80	6.82	3.86	4.08
Maneb											
Total Amount (Lbs AI) Applied	528	587	547	439	466	395	251	487	8	190	124
Avg Number of Apps/Season	2.7	2.8	2.9	2.9	3.8	3.5	3.5	3.2	2.3	2.5	2.7
Percent of Crop Treated	18	17	16	13	9	9	9	15	3	5	4
Avg App Rate (Lbs AI/Ac/Trt)	1.00	1.06	1.13	1.04	1.13	1.10	1.00	1.05	1.02	1.23	1.23
Seasonal App Rate (Lbs AI/Ac/Yr)	2.74	2.99	3.29	3.00	4.33	3.85	3.54	3.34	2.36	3.19	3.31
Metiram											
Total Amount (Lbs AI) Applied	62	50	31	neg	48	354	196	276	42	529	303
Avg Number of Apps/Season	2.1	1.8	1.7	neg	2.2	3.5	3.0	2.2	4.4	2.6	2.8
Percent of Crop Treated	3	3	1	neg	2	6	5	9	7	12	9
Avg App Rate (Lbs AI/Ac/Trt)	0.90	1.01	1.49	neg	1.27	1.52	1.49	1.47	1.27	1.46	1.34
Seasonal App Rate (Lbs AI/Ac/Yr)	1.88	1.78	2.48	neg	2.79	5.28	4.53	3.25	5.71	3.83	3.76
Total Acres Planted (Surveyed States) nr											
		1,131	1,068	1,118	1,140	1,147	797	944	99	1,108	898

Source: USDA National Agricultural Statistics Service, Agricultural Chemical Usage, Field Crops Survey, Various Years.

* Lbs ai applied and acres planted are in 1000's.

Table 2 summarizes USDA estimates for EBDC use on fall potatoes between 1990 and 2001. Among the three EBDCs, mancozeb had the most significant use on fall potatoes with an estimated 1.88 million lbs ai applied in 2001 (82% of total EBDC use). Maneb use on fall potatoes fell during this period from 528,000 lbs ai in 1990 to approximately 124,000 lbs ai (5% of total EBDC use) in 2001; while metiram use rose from 62,000 lbs ai to 303,000 lbs ai (13% of total EBDC use).

The increase in mancozeb use is primarily due to increases in the percent of crop treated. In 2001, an estimated 51% of the fall potato crop was treated with mancozeb compared with 26% treated in 1990. The seasonal application rates did not change significantly during this period. The NASS publications reported a high seasonal application rate in 1998 (6.82 lbs ai/acre/year); however, that estimate was based only on data reporting for just two states, Pennsylvania and Wisconsin, which historically have both had high use rates for mancozeb (%CT and application rates). The estimated 99,000 acres of fall potatoes planted in these two states amount to less than 10% of the US acreage planted annually. The USDA did not estimate pesticide use on fall potatoes during 2000, and resumed providing estimates for most of the major potato producing states in 2001.

Due to the increase in the percent of crop treated, the frequency of detecting EBDCs may be

underestimated by using the MBS survey data; however, the magnitude of the MBS residues is expected to be comparable to current residues due to similar application rates. In calculating average residues to be used for cancer risk assessment, the magnitude of residues is more important than the frequency, and therefore HED is not concerned about underestimating exposure from residues in potatoes. However, if dietary exposure assessments indicate significant exposure/risk contribution from residues in potatoes, a more refined analysis may be needed which addresses the potential increase in frequency of residues detected.

Table 3. EBDC Usage on Fresh and Processed Tomatoes.*

EBDC Use on Tomatoes, Fresh					
	1992	1994	1996	1998	2000
Mancozeb					
Total Amount (Lbs AI) Applied	434.6	860.9	433.5	581.4	506.0
Avg Number of Apps/Season	10.4	12.3	7.3	8.4	10.1
Percent of Crop Treated	38	54	63	52	42
Avg App Rate (Lbs AI/Ac/Trt)	1.13	1.36	1.07	1.47	0.98
Seasonal App Rate (Lbs AI/Ac/Yr)	11.74	16.65	7.79	12.35	9.91
Maneb					
Total Amount (Lbs AI) Applied	154.7	48.6	40.2	120.3	62.3
Avg Number of Apps/Season	6.9	6.3	6.5	4.4	3.8
Percent of Crop Treated	17	6	10	23	10
Avg App Rate (Lbs AI/Ac/Trt)	1.34	1.13	0.73	1.34	1.41
Seasonal App Rate (Lbs AI/Ac/Yr)	9.19	7.14	4.74	5.91	5.34
Acres Planted (Surveyed States)	105,100	103,900	88,700	90,500	120,570
EBDC Use on Tomatoes, Processed					
	1992	1994	1996	1998	2000
Mancozeb					
Total Amount (Lbs AI) Applied	11.6	41.4	50.8	206.1	86.9
Avg Number of Apps/Season	2.5	1.1	1.4	1.4	1.5
Percent of Crop Treated	1	10	12	50	16
Avg App Rate (Lbs AI/Ac/Trt)	1.49	1.23	0.94	1.02	1.22
Seasonal App Rate (Lbs AI/Ac/Yr)	3.69	1.34	1.31	1.46	1.85
Maneb					
Total Amount (Lbs AI) Applied	neg	10.0	18.0	26.1	12.7
Avg Number of Apps/Season	neg	1.2	1.3	1.2	1.2
Percent of Crop Treated	neg	2	3	8	3
Avg App Rate (Lbs AI/Ac/Trt)	neg	1.17	1.44	0.98	1.20
Seasonal App Rate (Lbs AI/Ac/Yr)	neg	1.36	1.90	1.19	1.45
Acres Planted (Surveyed States)	252,300	322,600	318,000	284,300	293,500

Source: USDA National Agricultural Statistics Service, Agricultural Chemical Usage, Vegetables, Various Years.

* Lbs ai applied and acres planted are in 1000's.

Table 3 summarizes EBDC usage on fresh and processed tomatoes between 1992 and 2000. Among the EBDCs, mancozeb has the most significant use on fresh tomatoes with an estimated

506,000 lbs ai applied in 2000 (89% of total EBDC use on fresh tomatoes), up from the 434,600 lbs ai applied in 1992. An estimated 62,300 lbs ai of maneb was also applied to fresh tomatoes in 2000 (11% of total EBDC use). The increase in mancozeb use is primarily due to an increase in the total acreage planted from 105,100 acres in 1990 to 120,570 acres in 2000 (NASS generally surveys most of the major producing states for that crop). Since the percent of crop treated (42% vs 38%) as well as the seasonal application rates (9.91 lbs ai/ac/yr vs 11.74 lbs ai/ac/yr) have not changed considerably, the frequency and magnitude of EBDC residues in the MBS data are considered to reflect current residues found in fresh tomatoes.

EBDC usage on processed tomatoes has increased since 1990: mancozeb use increased from 11,600 lbs ai to 86,900 lbs ai, while maneb use increased from negligible amounts to 12,700 lbs ai in 2000. The increase in mancozeb use on processed tomatoes is primarily due to changes in the percent of crop treated; approximately 16% of the processed tomato crop was treated in 2000, compared to only 1% in 1992. The seasonal application rates (average number of applications) for both mancozeb and maneb on processed tomatoes (%CT and seasonal application rates) are low relative to use on fresh tomatoes.

Based on current use patterns, a higher frequency of mancozeb detections in processed tomatoes is expected relative to the frequency of detected residues in the MBS data. Since the seasonal application rates have not changed considerably, the magnitude of the MBS residues is considered comparable to expected current average residues. The fact that processed tomato commodities tend to be blended diminishes the effect of the greater frequency of residues in terms of estimating dietary exposure and risk. While no adjustments to the MBS data are recommended for the current assessment, additional refinements may be needed, especially if residues in processed tomatoes constitute a significant contribution to the overall risk.

Table 4. EBDC Usage Estimates for Fresh and Processed Corn.*

Sweet Corn, Fresh					
Mancozeb	1992	1994	1996	1998	2000
Total Amount (Lbs AI) Applied	190.3	202.3	145.7	78.5	162.7
Avg Number of Apps/Season	4.7	4.7	4.0	3.1	4.9
Percent of Crop Treated	27	31	26	15	16
Avg App Rate (Lbs AI/Ac/Trt)	0.96	0.93	0.98	0.94	1.01
Seasonal App Rate (Lbs AI/Ac/Yr)	4.56	4.42	3.91	2.98	4.95
Maneb					
Total Amount (Lbs AI) Applied	19.4	*	25.4	*	*
Avg Number of Apps/Season	3.2	*	2.6	*	*
Percent of Crop Treated	5	*	10	*	*
Avg App Rate (Lbs AI/Ac/Trt)	0.83	*	0.65	*	*
Seasonal App Rate (Lbs AI/Ac/Yr)	2.68	*	1.69	*	*
Acreage Planted (Surveyed States)	154,100	163,900	145,500	179,180	204,100
Sweet Corn, Processed					
	1992	1994	1996	1998	2000
Mancozeb					
Total Amount (Lbs AI) Applied	254.9	56.8	*	neg	*

Table 4. EBDC Usage Estimates for Fresh and Processed Corn.[†]

Avg Number of Apps/Season	2.5	1.8	*	neg	*
Percent of Crop Treated	17	6	*	neg	*
Avg App Rate (Lbs AI/Ac/Trt)	1.19	1.11	*		*
Seasonal App Rate (Lbs AI/Ac/Yr)	2.99	1.99	*	neg	
Maneb					
Total Amount (Lbs AI) Applied	14.7	neg	neg	neg	neg
Avg Number of Apps/Season	1.9	neg	neg	neg	neg
Percent of Crop Treated	1	neg	neg	neg	neg
Avg App Rate (Lbs AI/Ac/Trt)	1.20	neg	neg	neg	neg
Seasonal App Rate (Lbs AI/Ac/Yr)	2.27	neg	neg	neg	neg
Acres Planted (Surveyed States)	486,300	503,400	416,600	439,000	419,800

Source: USDA National Agricultural Statistics Service, Agricultural Chemical Usage, Vegetables, Various Years.
neg = Percent of Crop Treated is negligible; no use reported among growers surveyed.

* = Insufficient reports to publish estimates.

[†] Lbs ai applied and acres planted are in 1000's.

Table 4 presents USDA estimates for EBDC usage on sweet corn during the 1992-2000 period. The table indicates that mancozeb use on fresh sweet corn has remained relatively constant (%CT fell slightly, while seasonal application rates rose slightly). The data also indicate that mancozeb use on processed sweet corn is negligible, as is maneb use on both fresh and processed sweet corn. Based on these data, MBS residues are conservative relative to expected current EBDC residues on both fresh and processed sweet corn.

Table 5. EBDC Use on Head Lettuce.*

	1992	1994	1996	1998	2000
Maneb					
Total Amount (Lbs AI) Applied	281.1	277.7	231.8	408.0	278.8
Avg Number of Apps/Season	1.8	2.2	1.6	1.9	2.1
Percent of Crop Treated	57	48	56	76	49
Avg App Rate (Lbs AI/Ac/Trt)	1.28	1.36	1.32	1.35	1.42
Seasonal App Rate (Lbs AI/Ac/Yr)	2.30	3.04	2.12	2.69	2.92
Acres Planted (Surveyed States)	206,000	191,000	194,900	198,600	196,700

Source: USDA National Agricultural Statistics Service, Agricultural Chemical Usage, Vegetables, Various Years.

* Lbs ai applied and acres planted are in 1000's.

Table 5 presents USDA estimates of EBDC usage on head lettuce between 1992 and 2000. Maneb use on head lettuce fluctuates from year to year: e.g., the percent crop treated attained a high of 76% in 1998, and a low of 48% (49%) in 1994. The seasonal application rates also fluctuate (e.g., high of 3.04 lbs ai/ac/yr in 1994), but do not have appeared to changed significantly relative to the 1992 levels.

Based on the usage data, the magnitude of EBDC residues found in the MBS data are expected to be comparable with residues expected to be found on head lettuce under current the current use pattern.



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